

Atellica® Solution

Atellica CH 930 Analyzer – Three issues identified in Atellica Solution Software V 1.19.2 and below

Our records indicate that your facility may have received the following product:

Table 1. Atellica® Solution Affected Product:

Product	Siemens Material Number (SMN)
Atellica CH 930 Analyzer	11067000

Reason for Urgent Field Safety Notice

The purpose of this communication is to inform you of issues with the Atellica CH 930 Analyzer listed in Table 1 above, installed with Atellica Solution software (SW) versions V1.19.2 or lower and to provide instructions on actions that your laboratory must take. These issues will be fixed in software version 1.20.

Siemens Healthcare Diagnostics Inc. has confirmed three issues:

Assays	Issue observed
Issue #1: Ecstasy (SMN# 11097518)	The test definitions allow for 20 day pack calibration interval instead of 15 days. Based on Siemens Healthineers' investigation, there is no impact to the performance of the Ecstasy assay due to the extended pack calibration.
Issue #2: Total Protein (SMN# 11097604)	The test definition allows for a 185 day lot calibration interval instead of 181 days. Based on Siemens Healthineers' investigation, there is no impact to the performance of the Total Protein assay due to the extended lot calibration.
Issue #3: Rheumatoid Factor (SMN# 11097618)	The test definition allows for a 30 days Onboard Stability (OBS) interval instead of 21 days. Based on Siemens Healthineers' investigation, there is no impact to performance of the Rheumatoid Factor (RF) assay concentrations of approximately 7 IU/mL and 45 IU/mL due to the extended OBS. At a RF concentration of 75 IU/mL, a maximum decrease in recovery of 9% was observed due to the extended OBS.

Risk to Health

Ecstasy and Total Protein	The risk to health due to this issue is negligible. There is no impact to assay performance for Ecstasy and Total Protein.
Rheumatoid Factor	The risk to health due to this issue is negligible. Patient samples with results above the reference interval for Rheumatoid Factor would have similar clinical interpretation. Mitigations include correlation to clinical history and presentation as well as to other laboratory diagnostic evaluation. Siemens Healthineers' is not recommending a review of previously generated results.

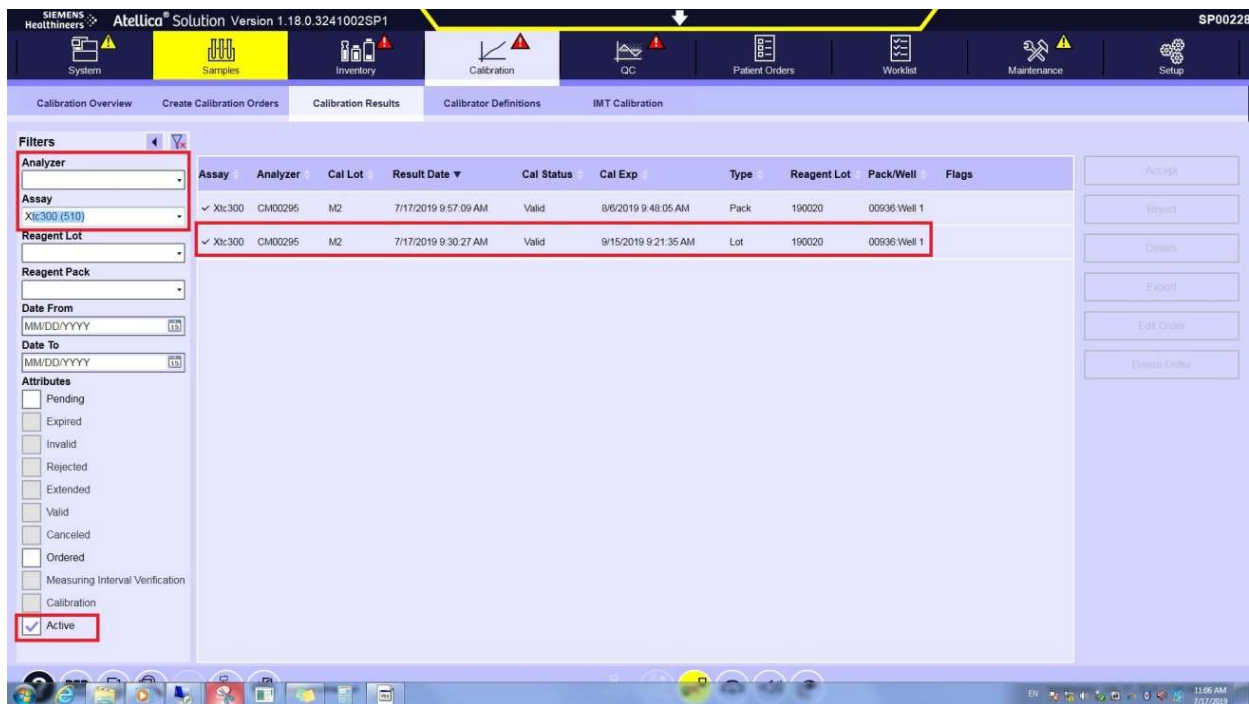
Actions to be Taken by the Customer

Issue #1: Atellica CH 930 Ecstasy (Xtc300 & Xtc500) Pack Calibration Workaround

1. Load Atellica CH Ecstasy (Xtc300/500) reagent packs onto the CH Analyzer. Refer to the Atellica Solution Online Help Section **Loading CH Reagents** for instructions.
2. Immediately perform a lot calibration. Refer to the Atellica Solution Online Help Section **Creating Assay Reagent Lot Calibration Orders** for instructions.
3. Upon completion and acceptance of the lot calibration, record the date and time the calibration was performed by navigating to **Calibration > Calibration Results** and filtering on the appropriate assay and analyzer. (Reference Figure 1. Calibration Results Screen)
4. If the test count in the well reaches zero before the 15 days elapses no additional action is required.
5. If the test count in the well does not reach zero before 15 days elapses, 15 days after the lot calibration was performed, a pack calibration must be performed. Refer to the Atellica Solution Online Help Section **Creating Assay Reagent Pack Calibration Orders** for instructions.
6. Upon completion and acceptance of the pack calibration, record the date and time the pack calibration was performed by navigating to **Calibration > Calibration Results** and filtering on the appropriate assay.
7. Perform steps 5 – 6 until either the well has zero tests left or has insufficient tests to perform another pack calibration upon expiration.
8. When the system switches wells, the already established lot calibration will be applied to the newly punctured well. When this happens, Navigate to **Inventory > Reagent Overview** select the onboard Xtc pack and under Reagent Details record the date and time that the second well was punctured. Fifteen days after the second well is punctured, a pack calibration must be performed. This process must be repeated until the well test count reaches zero.

Unrestricted

Figure 1. Calibration Results Screen



Issue #2: Atellica CH 930 Total Protein (TP) Lot Calibration Workaround

1. Navigate to **Calibration > Calibration Results** and select the TP Assay. (Reference Figure 1. Calibration Results Screen)
2. Record the date and time of the TP Lot calibration. A lot calibration will need to be performed 181 days from the recorded date.

Issue #3: Atellica CH 930 Rheumatoid Factor (RF) Onboard Stability Workaround

Reagent loading and Onboard Stability Recording

1. Load Atellica CH Rheumatoid Factor (RF) reagent packs onto the CH Analyzer. Refer to the Atellica Solution Online Help Section **Loading CH Reagents** for instructions.
2. Navigate to **Inventory > Reagent Overview** and select RF to view the Reagent Details. (Reference Figure 2. Reagent Overview Screen)
3. Record the date and time the reagent pack well(s) is opened. Please check status of each well in “Reagent Details”.
 - a. Condition #1: If both wells are punctured upon loading the reagent pack and/or the Atellica Software Version is <1.19, the entire pack must be unloaded after 21 days.

Unrestricted

Atellica CH 930 Analyzer – Three issues identified in Atellica Solution Software V 1.19.2 and below

Refer to the Atellica Solution Online Help Section **Unloading Reagents** for instructions.

- b. Condition #2: If only the first well is punctured upon loading the reagent pack and the Atellica software version is 1.19 and greater, please follow steps below for manually disabling a reagent pack well to utilize the second well. Once the second well is open for 21 days the entire pack must be unloaded from the CH analyzer.
- c. **NOTE:** If either Well 1 or Well 2 test count reaches zero before the 21 onboard stability expires, no additional action is required.

Figure 2. Reagent Overview Screen

Reagent	Inventory	Onboard Stability	Sequence	Calibration Status	Calibration Interval	Cal Type In Use	QC Status	Lot	Cal Eligibility
ALT	413	10 d 3 h	07333 / 06878	Ready	10 d 3 h	Lot	280715	280715	Pack
ALT	850	39 d 13 h	07473 / 06876	Ready	17 d 18 h	Lot	280715	280715	Lot and Pack
CO2_c	729	4 d 3 h	01053	Expired	0 d 0 h		190003	190003	Pack
Mg	391	39 d 13 h	03631 / 00342	Expired	0 d 0 h		280678	280678	Lot and Pack
RF	180	89 d 23 h	85215 / 02021	Expired	---		123456	123456	Lot and Pack
RPC1	418	56 d 13 h	00686 / 00690	Expired	---		190029	190029	
RPC2	418	49 d 13 h	03900 / 03853	Expired	---		190016	190016	
TP	1850	8 d 13 h	03441 / 02627	Ready	8 d 13 h	Lot	280568	280568	Lot and Pack
WBA	276	142 d 19 h	01017	Expired	---		190011	190011	
Xtc	100	89 d 23 h	00936 / 01024	Expired	---		190020	190020	Lot and Pack

Manually Disabling a Reagent Pack Well or Unloading a Reagent Pack from the CH Analyzer

For Atellica software versions 1.19 and greater:

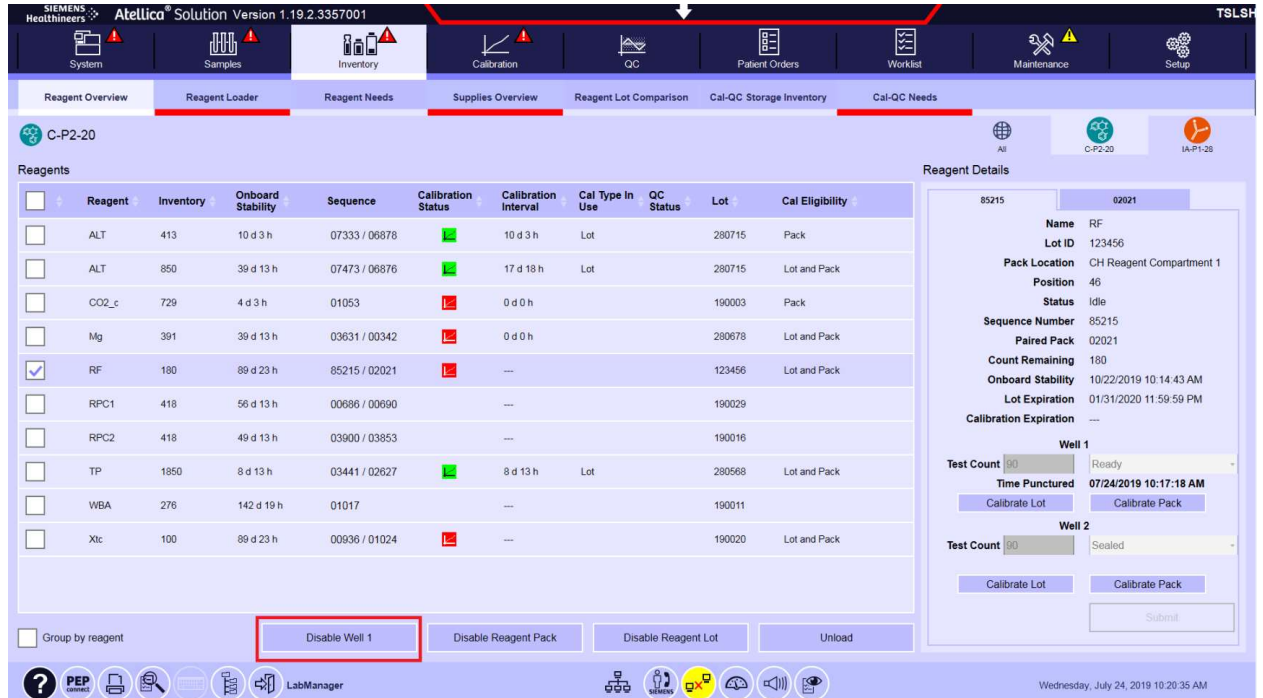
1. Log in as Lab Manager
2. Navigate to **Inventory > Reagent Overview** (Reference Figure 3. Reagent Overview Screen)
3. Locate and select the RF reagent.
4. Select the P1 Reagent Pack in Reagent Details
5. Select Disable Well 1

For Atellica Software Versions <1.19:

1. Remove the Reagent Pack from the CH Analyzer. Refer to the Atellica Solution Online Help Section **Unloading Reagents** for instructions.
2. Discard the reagent pack.

Unrestricted

Figure 3. Reagent Overview Screen



- Please review this letter with your Medical Director.
- Complete and return the Field Correction Effectiveness Check Form attached to this letter within 30 days.
- If you have received any complaints of illness or adverse health events associated with the product listed in Table 1, immediately contact your local Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Please retain this letter with your laboratory records and forward this letter to those who may have received this product.

We apologize for the inconvenience this situation may cause. If you have any questions, please contact your Siemens Healthineers Customer Care Center or your local Siemens Healthineers technical support representative.

Atellica is a trademark of Siemens Healthcare Diagnostics. Inc.

Unrestricted